

- (ii) combining one or more of the liquid extracts;
- (iii) adjusting the pH to about 6 to about 8; and
- (iv) mixing the one or more liquid extracts with a suitable pharmaceutical carrier.--

--71. A composition obtained by the method of claim 22.--

--72. A composition obtained by the method of claim 54.--

REMARKS

I. PENDING CLAIMS AND SUPPORT FOR AMENDMENT

Upon entry of the present amendment, claims 4-6, 8-9, 12-14, 22, 24-26, 29, 32, 36, 38-40, and 54-72 will be pending in the application. Claims 4-6, 8-9, and 12-14 have been amended to depend from claim 22. Claims 2, 3, 7, 10, 11, 15-21, 23, 27-28, 30-31, 33-35, 37, and 41-53 have been canceled without prejudice or disclaimer to the subject matter thereof. Note that although claims 28-31, 33-35, and 37 are readable on the elected invention, Applicant has incorporated these claims into claims 22, 29 and 32 for the sake of clarity and to more clearly define the invention.

The Examiner has withdrawn claims 2-21, 23-27, 32-35, and 41-53 from consideration. Applicant respectfully submits that the amendments to these claims

make them readable on the elected invention, and requests that the withdrawal of these claims be reconsidered.

Applicants have also added new claims 54-72. Support for the amendments to the claims and for the presentation of new claims appears throughout the specification, particularly at the bottom of page 16 through page 20.

II. REQUIREMENT FOR RESTRICTION

The Examiner has required restriction between Group I, containing claims 2-21, which the Examiner considers to be drawn to a composition; Group II, containing claims, which the Examiner considers to be drawn to a method of producing a composition; and Group III, containing claims 41-53, which the Examiner considers to be drawn to a method of treating. Applicants elected the claims of Group II, with traverse.

The Examiner continues to allege that the inventions of each group are patentably distinct from each other. In the response filed July 24, 2000, Applicant respectfully requested that the Examiner provide an example of how the products of Group I can be made by another process, for example extracts of *other* plants or by *organic synthesis*, as asserted by the Examiner. As Applicant has previously argued, the products of Group I, as claimed, recite plant material "selected from the group consisting of *Glinus lotoides*, *Ruta chalepensis*, *Hagenia abyssinica*, and *Milletia ferruginea*." There is simply no way to make extracts of these plants using "extracts

of other plants," as the Examiner has alleged, nor would synthetic methods produce the product as claimed (which is cast as an extract of *plant material*). The Examiner was requested to provide his proposed technique for organically synthesizing the claimed plant extracts so that Applicant could articulate an appropriate response, but the Examiner has not done so. Nonetheless, in an abundance of cooperation and in an effort to move this application to allowance, Applicant has amended various composition claims of Group I to depend from method claims of Group II in order to comply with the Examiner's restriction.

With respect to Group III, the Examiner also asserts that "the product as claimed can be used in a materially different process of using that product, e.g., treating patients for lowering cholesterol or controlling triglycerides -- which Applicant alleges cannot be possible since the extracts can only be prepared by the disclosed species." The meaning of this statement is unclear to Applicant. Applicant has not asserted that there are no other uses for the compositions formed by the claimed method. Neither has Applicant stated or implied that it cannot be possible to use the product formed by the claimed method for lowering cholesterol or controlling triglycerides. Again, however, in an abundance of cooperation and in an effort to move the case to allowance, Applicant has canceled method claims 41-53 without prejudice or disclaimer to the subject matter thereof.

III. REJECTIONS UNDER 35 U.S.C. § 102(b) and §103(a)

Claims 22, 38-39 and 40 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ageel et al. (BIOS ABSTRACT BA89:92285), a full copy of which is enclosed for the Examiner's convenience. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

In the alternative, claims 22 and 28-31, 36, 38-40 are rejected under 35 U.S.C. § 103(a) as being obvious over Ageel et al, Kavimani et al (CABA ABSTRACT 2000:53058) or Shah et al (SCISEARCH ABSTRACT 91:548657), full copies of which are also enclosed. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The Examiner asserts that each of these references teaches the extraction of plant material with a solvent that is within the scope of the claimed process. The Examiner concedes, however, that these references do not disclose additional solvent extraction. Nevertheless, the Examiner considers it obvious to one of ordinary skill in the art to add additional solvent extraction steps to maximize separation and to increase yield absent some unexpected difference in result due to the second process step.

As recognized by the Examiner, the Ageel reference does not teach or suggest conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents. The reference also does not teach or suggest adjusting

the pH of the solution to help elute or disassociate any compounds from their natural state in the plant material. Further, Ageel does not suggest or teach the use of *Glinus lotoides*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of solvents other than ethanol.

Also recognized by the Examiner, the Kavimani reference does not teach or suggest conducting multiple extractions with the solvent or conducting extractions with different or multiple solvents. The reference also does not teach or suggest adjusting the pH of the solution to help elute or disassociate compounds from their natural state in the plant material. Further, Kavimani does not suggest or teach the use of *Ruta chalepensis*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of solvents other than methanol.

The Shah reference also fails to teach or suggest conducting multiple extractions with the solvent, conducting extractions with different or multiple solvents, or adjusting the pH of the solution to help elute or disassociate any different or unknowns from their natural state in the plant material. Further, Shah does not suggest or teach the use of *Glinus lotoides*, *Hagenia abyssinica*, or *Millettia ferruginea*, or teach the use of solvents other than ethanol.

The references cited by the Examiner only refer to or teach preparations of *Glinus lotoides* and *Ruta chalepensis*. The Examiner has not found a reference that indicates a method of preparing a composition comprising *Hagenia abyssinica* and *Millettia ferruginea*. The references cited do not suggest a single extraction of these

plant materials, or multiple extractions, or pH adjustments as claimed by Applicant. Furthermore, Applicant's methods provide different compositions than those resulting from the extractions of the plant materials in the cited references.

Accordingly, because Applicant has deleted *Glinus lotoides* and *Ruta chalepensis* from the claim 22 and because the Examiner has cited no references teaching a method of extracting the remaining recited plant materials, Applicant respectfully asserts that claim 22 and the claims which depend therefrom are clearly allowable.

Additionally, as recognized by the Examiner, none of the references teach or suggest multiple extractions of any plant material, and none teach adjusting the pH of the composition. The Examiner has conceded that each reference describes only one extraction of the plant material, whereas Applicant claims multiple extractions. It cannot be considered obvious to one of ordinary skill in the art to perform multiple extractions when there is no such suggestion in the cited art. Nor can it be considered obvious to perform extractions with various or different solvents because, again, there is no such teaching or suggestion in the cited art.

On the other hand, the inventor has determined that multiple extractions often produce different peaks when the resulting compositions are run through Gas Chromatography/Mass Spectrometry ("GC/MS") as compared to compositions resulting from single extractions analyzed in this same way. This is not predictable or expected. Plants contain a variety of compounds that simply cannot be extracted out

by using one solvent, and the GC/MS results obtained by Applicant confirm this. When the inventor used multiple extractions, he was able to recover unknown or disassociated compounds that were not detectable after single extractions. Thus, by applying Applicant's method of multiple extractions, optionally using different solvents for different extractions, compositions containing compounds that previously had not been extracted or that experimenters were not aware even existed, were obtained.

Applicant is willing to provide Examiner with the above-described GC/MS results if the Examiner believes it would be helpful in advancing the prosecution of this application. However, Applicant does not believe that such results are necessary to patentability of the claimed compositions because, in Applicant's view, the Examiner has not established a *prima facie* case of obviousness.

Furthermore, the cited art does not suggest a method for providing a plant extract composition by extracting the plant material and then adjusting the pH of the plant material or resulting crude material. Applicant has determined that altering the pH (to either a basic or an acidic pH or both) helps extract or disassociate compounds from their natural state in the plant material in such a way that provides GC/MS peaks that are not obtained when the pH is not adjusted. This method provides new ways to identify compounds present in the studied plant materials. The claimed method of multiple extractions and/or pH adjustment of the plant materials is not taught by the cited references, nor is it obvious to one of ordinary skill in the art.

AMENDMENT AND RESPONSE UNDER 37 CFR §1.111
U.S.S.N. 09/442,256
Filed: November 17, 1999



CONCLUSION

Because Applicant has provided a novel and nonobvious method to isolate and provide extracts of plant materials and to determine the active compounds in those plant materials, an early favorable allowance of the pending claims is earnestly solicited.

Applicants believes that no fees are due, but if mistaken, please charge any additional fees or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,

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